

### **REMARKS**

This communication is in Response to the Office Action mailed on October 31, 2007. Claims 27 and 36 have been amended. Claims 37 and 46-47 have been cancelled. Claims 27-36 and 38-45 are currently pending.

In view of the above amendments and below remarks it is believed that the pending claims are in a condition for allowance. Reconsideration of the pending claims and an indication of allowance are therefore respectfully requested.

#### **Double Patenting**

Claims 27, 36-37, and 46-47 were provisionally rejected on the ground of nonstatutory obviousness-type double patent as being unpatentable over claims 22-24 of copending Application No. 10/698,213. A terminal disclaimer will be submitted after allowance of the present application to obviate this rejection in order to expedite issuance. The Applicants therefore request that this rejection be held in abeyance until claims are indicated as allowable.

#### **Rejection of the Claims Under 35. U.S.C. § 103**

Claims 27-32, 34, 36-43, and 45-47 have been rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,231,591 to Ashvin H. Desai ("Desai") in view of U.S. patent No. 5,486,161 to Ronald G. Lax et al. ("Lax") in further view of U.S. patent No. 7,037,294 to Ronald B. Luther et al. ("Luther"). Claims 37 and 46-47 were cancelled and so the rejection of these claims is moot. Moreover, no combination of Desai, Lax, and Luther discloses, teaches, or suggests all of the limitations in the claims. Independent claims 27 and 36 therefore do not read upon any combination of these references. Withdrawal of this rejection is therefore respectfully requested.

Amended claim 27 includes limitations to a method for delivering a denervating agent to a prostate gland that includes "inserting an imaging apparatus into a rectum of a patient" and thereafter "delivering the denervating agent to the prostate gland via a lumen of the needle." The method further includes "rotating and moving the shaft with respect to the prostate gland to position the distal end of the shaft in proximity to a second location of the prostate gland while the shaft is still inserted into the rectum of the patient" and "inserting the needle into the prostate

gland at the second location.” In addition, amended independent claim 36 is directed towards a “system for delivering a denervating agent to a prostate gland” including “an imaging apparatus sized for insertion into a rectum of a patient” that includes a shaft and “a handle for holding the shaft, and a wheel that permits rotation of the shaft relative to the handle and about the longitudinal axis while the shaft is inserted into the rectum.”

The combination of Desai and Epstein does not teach, suggest, or disclose all of the elements of either claim 27 or 36.

Desai teaches a hollow core needle that is inserted into a body for the delivery of various biological agents to a target area. Abstract. Desai includes the use of an endoscopic instrument to help guide the needle. Lax discloses a stylet ablation device for delivering energy or substances to the tissue. One embodiment of Lax is directed toward a radiofrequency ablation device that includes a rigid hollow needle and an RF electrode. As stated in the Office Action, however, “Desai and Lax et al. are silent with a wheel used to rotate the orientation of the needle.” October 31, 2007 Office action at 4. The office action cites to Luther to fill in the disclosure missing from Desai and Lax.

The Office Action cites to Luther as disclosing “a needle having a wheel which permits rotation of the needle to a desired orientation.” Office Action, at 4. Luther does teach a hollow needle that can be “rotated by rotating the syringe barrel adapter.” However, the needle is not intended to be rotated while inserted in the patient. Rather, “rotation of the hollow needle 120 while the hollow needle 120 is positioned within a patient’s vasculature presents the risk of injuring the patient with the rotating beveled tip 122.” Luther, col. 4, lines 13-17. When the needle is inserted into the patient Luther allows the “user to rotate the syringe barrel adapter 130 as required for convenience, without simultaneously rotating the hollow needle.” In other words, Luther allows the user to rotate the syringe barrel adapter 130 to a more convenient position without affecting the orientation of the needle that is inserted into the patient. This is how the needle is rotatable compared to the syringe barrel adapter 130, but this is not a rotatable needle as disclosed, implemented, and claimed in the present invention.

Claims 27 and 36 include “rotating and moving the shaft with respect to the prostate gland to position the distal end of the shaft in proximity to a second location of the prostate gland

while the shaft is still inserted in to the rectum of the patient” and “a handle for holding the shaft, and a wheel that permits rotation of the shaft relative to the handle,” respectively.

Luther therefore does not teach, suggest, or disclose all of the limitations of independent claims 27 and 36. Luther, in fact, teaches away from the present invention by stating that adjustment of the orientation for insertion of the needle when the needle is in the patient is dangerous. Luther does not cure the deficiencies of Desai and Lax. Withdrawal of this rejection is therefore respectfully requested.

Dependent claims 28-35 and 38-45 depend directly or indirectly on one of independent claims 27 and 36. These claims are therefore allowable for at least the same reasons as given above. Withdrawal of the rejection of claims 28-35 and 38-45 is therefore respectfully requested.

### CONCLUSION

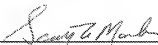
In view of the foregoing amendments, Applicants respectfully request reconsideration and allowance of the claims as all rejections have been overcome. Early notice of allowability is kindly requested.

The Examiner is respectfully requested to contact the undersigned by telephone at 763.505.0409 or by e-mail to [scott.a.marks@medtronic.com](mailto:scott.a.marks@medtronic.com) with any questions or comments.

Please grant any extension of time, if necessary for entry of this paper, and charge any fee due for such extension or any other fee required in connection with this paper to Deposit Account No. 13-2546.

Respectfully submitted,

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